DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 21, 2014

Spineart
Mr. Franck Pennesi
Director of Industry and Quality
International Center Cointrin
20 route de pré-bois, CP 1813
1215 Geneva 15 – SWITZERLAND

Re: K141508
Trade/Device Name: ROMEO® 2 PAD Posterior Axial Device
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: June 5, 2014
Received: June 6, 2014

Dear Mr. Pennesi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141508

Device Name

ROMEO®2 PAD Posterior Axial Device

Indications for Use *(Describe)*

The ROMEO®2 PAD Posterior Axial Device is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e.,fracture or dislocation) and /or tumor. The ROMEO®2 PAD Posterior Axial Device is not intended for standalone use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510k

ROMEO®2 PAD

Posterior Axial Device

510(k) SUMMARY

Submitted by	**SPINEART** International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Date Prepared	August 18th 2014
Common Name	Spinous Process Plate
Trade Name	ROMEO®2 PAD Posterior Axial Device
Classification Name	Spinal interlaminal fixation orthosis
Class	II
Product Code	PEK
CFR section	888.3050
Device panel	Orthopedic
Legally marketed predicate devices	SP-Fix® by Globus Medical (K102195); Axle® System by X-Spine (K112592, K130438); Spinous Process Fusion Plate by Lanx (K071877, K092536); Affix® spinous Process Plate by NuVasive (K073278, K131238) and Spire® Spinous Process Plate by Medtronic (K032037).
Indications for use	The ROMEO®2 PAD Posterior Axial Device is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e.,fracture or dislocation) and /or tumor. The ROMEO®2 PAD Posterior Axial Device is not intended for standalone use.

Description of the device	The ROMEO®2 PAD is a Spinous Process Fixation device consisting of two titanium plates linked by a titanium cylinder that is used to perform immobilization of spinous processes of adjacent vertebras and thus provide supplemental stabilization of spinal segments to facilitate fusion. The device is locked and secure automatically at the same time.
Technological Characteristics	The plates include spikes on their opposing faces to provide attachment to bone. The mobile plate can translate along the titanium cylinder and includes some features that insure continuous locking at any position. The locking anti-back-out system maintains the plates in the desired position and pressed firmly against the spinous processes. The ROMEO®2 PAD is available in a range of sizes to fit the anatomical needs of a variety of patients. Components are provided pre-assembled and delivered sterile (gamma sterilization) with dedicated surgical instruments (reusable – provided non sterile). As was established in this submission, the subject ROMEO®2 PAD is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including design, labeling/intended use, material composition, mechanical performance and function.
Discussion of Testing	The following non-clinical tests were conducted on ROMEO®2 PAD: Static and dynamic compression bending, static and dynamic torsion according to an in-house testing protocol inspired of ASTM F1717; Static Axial disassociation and dynamic compression tension according to an in-house testing protocol.
Conclusion	The ROMEO®2 PAD Posterior Axial Device is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. The subject and predicate devices have similar technological characteristics.